REMARKS

Entry of the foregoing and further and favorable reconsideration of the subject application in light of the following remarks pursuant to and consistent with 37 C.F.R. § 1.116, are respectfully requested.

By the foregoing amendment, claim 2 has been deleted, without prejudice or disclaimer to the subject matter disclosed therein. The subject matter of claim 2 has been incorporated into claim 1. Applicants reserve the right to pursue the subject matter canceled as a result of this amendment in a continuation application. Claims 4, 5, 6, 11-16 and 19-20 have also been amended merely to clarify the claims, as discussed in more detail below. Furthermore, new claim 21 has been added. Support for new claim 21 may be found in original claim 1 and, at the very least, on page 4, lines 1-13, of the application as filed, and in claim 3 as filed. No new matter has been added by the present amendment.

Objections to the Claims

Claim 4 has been objected to for reciting "concentration of caffeine of between," which is purportedly unclear. Claim 4 has been amended to clarify the claim, thus rendering this objection moot.

Claim 11 has been objected to for reciting "weigh" rather than "weight." Claim 11 has been amended to delete "weigh" and replace it with "weight," thereby rendering this objection moot.

Rejection of Claims 1-20 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-20 have been rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

The Examiner purports that claims 1-20 are indefinite because the term "extract" is unclear. Applicants respectfully disagree.

Determining whether a claim is indefinite requires an analysis of "whether one skilled in the art would understand the bounds of the claim when read in light of the specification. . . If the claims read in light of the specification reasonably apprize those skilled in the art of the scope of the invention, [section] 112 demands no more." *Credle v. Bond*, 30 USPQ2d 1911, 1919 (Fed. Cir. 1994).

On page 10 of the specification, the applicant an exemplary means of extracting the green tea leaves using an ethanol extraction. However, the applicant states that the disclosed means is not limiting, and that other means of extracting the green tea leaves may be used, including varying the proportions of water and ethanol or by using other solvents, such as water, ethyl acetate, methanol, etc., alone or in combination. As stated by the applicant, the choice of solvents selected will make it possible to vary the catechol and caffeine content. One of skill in the art would know how to manipulate the extraction process, by using different extraction methods, to obtain green tea extracts having different concentrations of caffeine and catechol. Thus, one of skill in the art would understand the metes and bounds of the claim when read in light of the specification. In light of this, it is believed that this rejection of claims 1-20 should be withdrawn.

The Examiner purports that claim 5 is indefinite for containing functional language in a composition claim. Claim 5 has been amended to remove the functional language from the claim, thereby clarifying that the claim is drawn to a composition titrated so that a daily dose of the composition contains from 250 mg to 500 mg of catechols, and from 50 mg to 200 mg of caffeine. In light of this amendment to claim 5, withdrawal of this rejection is believed to be in order.

Claims 6-10 and 17-18 have been rejected for purportedly being indefinite for claiming a method of manufacturing, but purportedly not containing steps for manufacturing. The claims have been amended to recite that the method of manufacturing comprises obtaining an extract or powder of green tea by extraction of green tea, thereby clarifying the claim by providing proper functional language. In light of this amendment to the claims, withdrawal of this rejection is believed to be in order.

Claims 11-15 and 19-20 are purportedly indefinite for reciting the phrase "enhance his or her figure." According to the Examiner, the recited phrase is vague and not clearly defined. The Examiner also purports that the phrase "which is as low as desired" is not clearly defined. The claims have been amended to remove the phrase "enhance his or her figure" and to recite "to maintain a desired weight level," thereby rendering this rejection moot. In light of this amendment to the claims, withdrawal of this rejection is believed to be in order.

Claims 12-15 purportedly lack antecedent basis and fail to properly limit the base claim from which they depend. Claims 12-15 have been amended to clearly provide

antecedent basis and to clearly limit the base claim from which they depend. In light of the amendments to claims 12-15, withdrawal of this rejection is believed to be in order.

The Examiner also purports that claim 15 is indefinite because the term "daily dose" is unclear. Claim 15 has been amended to make clear what is meant by the term "daily dose." In light of the amendment to claim 15, withdrawal of this rejection is believed to be in order.

The Examiner purports that claim 16 is indefinite for not properly limiting claim 5, from which is depends. Claim 16 has been amended to clearly limit claim 5, thereby rendering its rejection moot.

Finally, claims 19-20 are allegedly indefinite for not reciting functional language. Claims 19-20 have been amended to properly recite functional language, thereby rendering their rejection moot.

In light of the above, withdrawal of these rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Rejection of Claims 1-10 and 16-18 Under 35 U.S.C. § 102(b)

Claims 1-10 and 16-18 have been rejected under 35 U.S.C. § 102(b) for purportedly being anticipated by Hara (U.S. Patent No. 4,673,530). For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

The present invention is drawn to compositions for curing and preventing obesity comprising an extract of green tea containing from 20-30% by mass of catechols expressed

as epigallocatechol gallate. The composition of the present invention can optionally contain from 5-10% by mass of caffeine. The present invention is also drawn to methods of manufacturing the compositions of the present invention.

Hara discloses the production of a specific extract of tea intended for use as an antioxidant. The object of the Hara invention is to use the tea extract in very low proportions in foods (10, 20 and 50 ppm) to protect the foods against the oxidation produced on contact of the food with atmospheric oxygen. Hara limits the application of the antioxidant properties of this tea extract to the use in salad oil and bacon. Therefore, the only disclosure in Hara for the use of the tea extract is as a technological additive for manufacturing foods. Hara does not disclose or suggest using their tea extract for treating or preventing obesity in a man. As discussed above, the only use disclosed by Hara for their tea extract is as an antioxidant in food.

Furthermore, although Hara discloses that their extracts contain at least about 30% tannin, typically about 70% tannin, there is no indication in Hara as to their means of determining tannin content. Therefore, there is no way to determine if their method of determining tannin content is accurate, and thus it would be difficult to compare the Hara disclosure regarding tannin content to the present invention, which relies on epigallocatechol gallate content.

Hara also does not disclose the presence of caffeine, in any concentration, in the extracts of their invention. In fact, contrary to the Examiner's assertion on page 6 of the Official Action that "Hara did not specifically state the concentration of caffeine in the composition. . . Thus, this product also contained the claimed ranges of caffeine because it

was inherent to the composition," as stated in Hara in column 2, line 19, all of the caffeine was removed from their extract. The method of Hara includes a step wherein the extract containing solution is washed with chloroform, which removes all impurities, including caffeine, from the solution. See also Example 1, column 3, line 12; Example 2, column 3, line 57; Example 3, column 4, line 10; Example 5, column 4, line 51; and Examples 6-9, column 5, line 2. It is therefore obvious that the object of the extraction process described in the Hara patent is to completely remove the caffeine by washing with chloroform. Thus, at the very least, new claim 21 should be patentable, since it is drawn to a composition comprising caffeine, which clearly the prior art does not disclose.

In light of these remarks, applicant respectfully requests withdrawal of this rejection under 35 U.S.C. § 102(b).

Rejection of Claims 11-15 and 19-20 Under 35 U.S.C. § 102(b)

Claims 11-15 and 19-20 have been rejected under 35 U.S.C. § 102(b) for purportedly being anticipated by Yuchi et al (JP 60114153). For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

As discussed above, the present invention is drawn to compositions for curing and preventing obesity comprising an extract of green tea containing from 20-30% by mass of catechols expressed as epigallocatechol gallate. The composition of the present invention can optionally contain from 5-10% by mass of caffeine. The present invention is also drawn to methods of manufacturing the compositions of the present invention.

Yuchi et al discloses a food containing an extract of tea, wherein the food purportedly promotes lipid metabolism. Yuchi et al indicate that the foods may be a snack, a sweet, a biscuit or a drink. Each of the listed foods correspond to calorific products (sugars, starches, etc.) and thus would be incompatible with a treatment for obesity. For example, the soft drink formulation contains 34 g of sugar and 65 g of apple juice (rich in sugar). Yuchi also disclose that their extracts are capable of reducing the neutral fats of the liver; eliminating the increase in fatty acids, lipid peroxidation, etc.; eliminating the accumulation of total cholesterol and of peroxidized lipids in the liver; and improving liver functions. However, these properties are not explained in the document and have not been the subject of scientific publications. Furthermore, there is no indication in Yuchi et al or in the prior art as to how these properties may effect obesity.

Moreover, the phrase "to metabolize lipids" has no scientific meaning, and thus it is unclear what the extracts disclosed by Yuchi et al can be used for. What lipids do they purportedly metabolize? What metabolic pathway do they follow? Are the lipids simply converted or used as energy substrate or removed?

The present application claims specific and scientifically demonstrated pharmacological properties, namely an increase in thermogenesis. The attached publications (Dulloo et al, *Am. J. Clin. Nutr. 70:*1040-1045 (1999), and Dulloo et al, *Int'l J. Obesity 24:*252-258 (2000), attached hereto as Exhibits A and B, respectively), each published after the priority date of the above-identified application, demonstrate that the extract of green tea AR25 (the subject matter of the present application) has the property of stimulating *in vitro* thermogenesis by synergistic activity between catechols (mainly

epigallocatechol gallate) and caffeine, this synergistic activity occurring for well-defined proportions of these two constituents. This stimulation of thermogenesis has been confirmed in a clinical study in man, in which an inhibition of gastric lipases was observed, thus reducing the absorption of dietary lipids (See Juhel et al, *J. Nutr. Biochem.* *11*:45-51 (2000), attached hereto as Exhibit C).

Kuchi et al discloses that various grades of tea may be used in their invention, including black tea, which implies that the extract obtained by this process is intended to have a chemical composition and thus properties that are fundamentally different from the extract obtained from green tea.

The present invention relates exclusively to an extract of green tea leaves which have not undergone any fermentation step. As was pointed out in the application, the tea leaves may, after harvesting, undergo a fermentation resulting in a degradation of the chemical substances they contain and in particular catechols. Tea leaves which have undergone fermentation are called black tea leaves. Tea leaves which have not undergone fermentation, and instead are dried immediately after harvesting, are called green tea leaves. Thus, there is a dramatic difference in the concentration of catechols between green tea leaves and black tea leaves, since the fermentation process undergone to obtain black tea leaves results in a degradation of catechols. Since Kuchi et al discloses that their invention can use black tea leaves, it is clear that they were not concerned with the concentration of catechols in their extract. Therefore, Kuchi et al could not possibly disclose or suggest a composition comprising an extract of green tea containing from 20-50% by mass of catechols, expressed as EGCG.

Furthermore, the extraction process used by Kuchi et al would obtain an extract very different from the extract obtained by the process of the present invention. The extraction process used by Kuchi et al comprises the following steps:

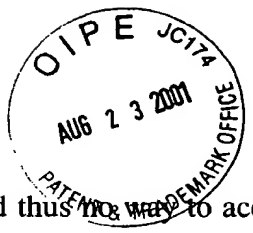
(i) extraction of a tea with a acetone/water mixture, the proportions of which are not defined. Given that water is a very polar solvent and acetone is among the least polar solvents, this first extraction step may be carried out with a mixture of very polar or very apolar solvents, depending on whether or not the water is largely predominant or in very low proportion. In the example given, the acetone:water proportion is 1:1, corresponding to an average polarity capable of extracting catechols and caffeine;

(ii) evaporation of the acetone; and

(iii) successive extraction with chloroform and then with ether and (for the fermented, i.e. black, tea only) with ethyl acetate. The extracts obtained from each of these extractions contain the following:

- chloroform extract: extract contains no catechols or caffeine;
- ether extract: extract contains no catechols or caffeine;
- ethyl acetate extract (used for black tea only): extract contains only catechols, not caffeine; and
- water extract: extract contains only caffeine.

The end result of the Kuchi et al extraction process are extracts which do not correspond to the extract described in the present application, which are extracts of green tea which comprise catechols and optionally caffeine. Furthermore, even if the extracts obtained by Kuchi et al did contain catechols and caffeine, there is no way to determine the amounts



contained and thus it was to accurately compare the extracts obtained to the extracts of the present invention.

In light of the above remarks, applicant respectfully requests withdrawal of this rejection under 35 U.S.C. § 102(b).

CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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Attachment to Amendment and Reply dated August 23, 2001

Marked-up Claims 1, 4, 5, 6, 11-16 and 19-20

1. (Twice Amended) A composition for the curative and prophylactic treatment of obesity, comprising an extract of green tea containing from 20% to [50] 30% by mass of catechols expressed as epigallocatechol gallate (EGCG).

4. (Twice Amended) A composition according to Claim 1, wherein [the extract of green tea has a] the ratio of the concentration of catechols to the concentration of caffeine in the extract of green tea is [of] between 2 and 10.

5. (Twice Amended) A composition according to Claim 1, wherein the extract of green tea is titrated so that [as to allow the administration of] a daily dose of the composition contains from 250 mg to 500 mg of catechols [per day], and from 50 mg to 200 mg of caffeine [per day].

6. (Twice Amended) A method of manufacturing a medicinal product which has antilipase and/or thermogenic properties, and which is intended for the curative and prophylactic treatment of obesity, comprising obtaining [using] an extract or powder of green tea by extraction of green tea.

11. (Twice Amended) A method for the esthetic treatment of a human being [in order to enhance his or her figure], wherein said method comprises the oral administration

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Marked-up Claims 1, 4, 5, 6, 11-16 and 19-20

of a catechol-enriched extract of green tea in order to bring about a loss of weight [weigh] or to maintain a desired weight level [which is as low as desired].

12. (Twice Amended) A method according to Claim 11, wherein said oral administration comprises administration of a [the] extract of green tea containing [contains] from 20% to 50% by mass of catechols expressed as epigallocatechol gallate (EGCG).

13. (Twice Amended) A method according to Claim 11, wherein said oral administration comprises administration of an [the] extract of green tea containing [contains] from 5% to 10% by mass of caffeine.

14. (Twice Amended) A method according to Claim 11, wherein said oral administration comprises administration of an [the] extract of green tea having a ratio [ration] of the concentration of catechols to the concentration of caffeine of between 2 and 10.

15. (Twice Amended) A method according to Claim 11, wherein said oral administration comprises administration of a daily dose of an [the] extract of green tea [is titrated so as to allow the administration of a daily dose of from] comprising 250 mg to 500 mg of cathecols [per day], and from 50 mg to 200 mg of caffeine [per day].

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Marked-up Claims 1, 4, 5, 6, 11-16 and 19-20

16. (Twice Amended) A composition according to Claim 5, wherein [the extract of green tea is titrated so as to allow the administration of a] said daily dose of the composition comprises about 375 mg of catechols [per day,] and about 150 mg of caffeine [per day].

19. (Amended) A method according to Claim 12, wherein said oral administration comprises administration of an [the] extract of green tea containing [contains] from 20% to 30% by mass of catechols expressed as epigallocatechol gallate (EGCG).

20. (Amended) A method according to Claim 15, wherein said oral administration comprises administration of a daily dose of an [the] extract of green tea [is titrated so as to allow the administration of a daily dose of from] comprising about 375 mg of catechols [per day,] and about 150 mg of caffeine [per day].